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EXAMINER	
HENKEL, DANIELLE B	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,964	SWEET ET AL.	
	Examiner	Art Unit	
	DANIELLE HENKEL	1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-19,21-23,25,27-30 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-19,21-23,25,27-30 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 2/22/11 has been entered and fully considered.

2. Claims 1-12, 14-19, 21-23, 25, 27-30, and 32-36 remain pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-2, 6-8, 10-12, 14-16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over KALRA (US 5948359) in view of TSEUNG (US 2003/0099573) and further in view of WANG (US 5900045).

a. With respect to claim 1, KALRA discloses an automatic staining apparatus comprising at least one removable reagent container positioned within a reagent section (Column 9, lines 15-20); at least one slide positioned within a slide section (slide holder) (Column 9, lines 25-27); wherein the robotic element (movable arm with Z head) is configured to move above the reagent section and above the slide section during a staining process (Column 9, lines 32-33, Figure 2); wherein the reagent section is situated to enable the at least one removable reagent container to be added or removed from the apparatus without interrupting the movement of the robotic element during the staining process (Column 9, lines 32-33, Figure 1); wherein the robotic element comprises an optical sensor (laser bar-code scanner) configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process (Column 8, lines 20-25, Column 12, lines 22-23); a control element (control unit) to which the robotic element is responsive, the control element configured to monitor insertion or removal of the at least one removable reagent container during the staining process (Column 5, lines 43-48, Column 16, lines 46-63). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a

reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime

without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

b. With respect to claim 2, KALRA discloses the optical sensor (bar-code scanner) is adapted to locate pre-selected reference features (bar codes in predetermined locations) for self-calibration (calibrate arm for specific staining protocol) of the robotic element (Column 5, lines 38-45, Column 8, lines 1-25, Column 15, lines 54-59).

c. With respect to claim 6, KALRA discloses a method of identifying at least one property in an automatic staining apparatus comprising the steps of providing at least one sample on a slide positioned within a slide section (slide holder) (Column 9, lines 25-27, Column 13, lines 52-54), providing at least one reagent container positioned within a reagent section (Column 9, lines 15-20); wherein the robotic element (movable arm with Z head) is configured to move above the reagent section and above the slide section during a staining process (Column 9, lines 32-33, Figure 2); wherein the at least one reagent container is capable of being added or removed from the apparatus without interrupting the staining process (Column 9, lines 32-33, Figure 1); providing the robotic element with an optical sensor (laser bar-code scanner) configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining

process (Column 8, lines 20-25, Column 12, lines 22-23); recording relevant image data (saving bar code information) (Column 16, lines 58-60); recording calibration reference points of the apparatus (bar codes location indicator) (Column 5, lines 38-45, Column 8, lines 1-25, Column 15, lines 54-59); feeding image data (bar codes) to a control element (computer) to which said robotic element is responsive (Column 8, lines 20-25) configured to monitor insertion or removal of the at least one reagent container during the staining process (Column 5, lines 43-48, Column 16, lines 46-63). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or

removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

d. With respect to claim 7, KALRA discloses a method of staining samples in an automatic staining apparatus comprising the steps of providing at least one sample on a slide positioned within a slide section (slide holder) (Column 9, lines 25-27, Column 13, lines 52-54), providing at least one reagent container positioned within a reagent section

(Column 9, lines 15-20); wherein the robotic element (movable arm with Z head) is configured to move above the reagent section and above the slide section during a staining process (Column 9, lines 32-33, Figure 2); wherein the at least one reagent container is capable of being added or removed from the apparatus without interrupting the staining process (Column 9, lines 32-33, Figure 1); providing the robotic element with an optical sensor (laser bar-code scanner) configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process (Column 8, lines 20-25, Column 12, lines 22-23); recording relevant image data (saving bar code information) (Column 16, lines 58-60); recording calibration reference points of the slide racks (bar code location indicator) (Column 5, lines 38-45, Column 8, lines 1-25, Column 15, lines 54-59); feeding image data (bar codes) to a control element (computer) to which said robotic element is responsive (Column 8, lines 20-25), configured to monitor insertion or removal of the at least one reagent container during the staining process (Column 5, lines 43-48, Column 16, lines 46-63). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below

robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being

configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

e. With respect to claim 8, KALRA discloses an automatic staining apparatus comprising at least one reagent container positioned within a reagent section (Column 9, lines 15-20); at least one sample on a slide positioned within a slide section (slide holder) (Column 9, lines 25-27, Column 13, lines 52-54); wherein the robotic element (movable arm with Z head) is configured to move above the reagent section and above the slide section during a staining process (Column 9, lines 32-33, Figure 2); wherein the reagent section is situated to enable the at least one reagent container to be added or removed from the apparatus without interrupting the movement of the robotic element during the staining process (Column 9, lines 32-33, Figure 1); wherein the robotic element comprises an optical sensor (laser bar-code scanner) configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process (Column 8, lines 20-25, Column 12, lines 22-23); and located pre-selected reference features (bar codes in predetermined locations) for self-calibration (calibrate arm for specific staining protocol) of the robotic element (Column 5, lines 38-45, Column 8, lines 1-25, Column 15, lines 54-59); and a control element (computer) to which said robotic element is responsive (Column 8, lines 20-25), configured to monitor insertion or removal of the at least one reagent container during the staining process (Column 5, lines 43-48, Column 16, lines 46-63). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one

reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line

controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

f. With respect to claim 10, KALRA discloses an automatic staining apparatus comprising at least one reagent container positioned within a reagent section (Column 9, lines 15-20); at least one sample on a slide positioned within a slide section (slide holder) (Column 9, lines 25-27, Column 13, lines 52-54); wherein the robotic element (movable arm with Z head) is configured to move above the reagent section and above the slide section during a staining process (Column 9, lines 32-33, Figure 2); wherein the reagent section is situated to enable the at least one reagent container to be added or removed from the apparatus without interrupting the movement of the robotic element during the staining process (Column 9, lines 32-33, Figure 1); wherein the robotic element comprises an optical sensor (laser bar-code scanner) configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process (Column 8, lines 20-25, Column 12, lines 22-23) and image at least one optical

identification element (Column 8, lines 20-25); and a control element (computer) to which said robotic element is responsive (Column 8, lines 20-25), configured to monitor insertion or removal of the at least one reagent container during the staining process using the optical identification element (Column 5, lines 43-48, Column 8, lines 20-25, Column 16, lines 46-63). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates

a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

g. With respect to claims 11-12 and 16, the optical identification elements in the form of barcodes as taught by KALRA are by definition multiple iterations of lines in patterns which may repeat (redundant) (Column 8, lines 1-10).

h. With respect to claims 14-15, KALRA teaches optical identification elements in the form of a barcodes (Column 8, lines 1-10). It would have been obvious to one having ordinary skill in the art to use two dimensional high resolution symbology or data matrix codes in the optical identification art and selection of any of these known equivalents to

use as slide identification in place of a barcode would be within the level of ordinary skill in the art (MPEP 2144.06).

i. With respect to claim 36, KALRA discloses a method of staining samples in an automatic staining apparatus comprising the steps of providing at least one slide positioned within a slide section (slide holder) (Column 9, lines 25-27, Column 13, lines 52-54), providing at least one removable reagent container positioned within a reagent section (Column 9, lines 15-20); wherein the robotic element (movable arm with Z head) is configured to move above the reagent section and above the slide section during a staining process (Column 9, lines 32-33, Figure 2); wherein the at least one reagent container is capable of being added or removed from the apparatus without interrupting the staining process (Column 9, lines 32-33, Figure 1); providing the robotic element with an optical sensor (laser bar-code scanner) configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process (Column 8, lines 20-25, Column 12, lines 22-23); recording relevant image data (saving bar code information) (Column 16, lines 58-60); feeding image data (bar codes) to a control element (computer) to which said robotic element is responsive (Column 8, lines 20-25), configured to monitor insertion or removal of the at least one removable reagent container during the staining process (Column 5, lines 43-48, Column 16, lines 46-63). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable

reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037).

6. Claims 3, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over KALRA (US 5948359) in view of TSEUNG (US 2003/0099573) as applied to claims 1-2, 6-8, 10-12, 14-16 and 36 above, and further in view of RHETT (US 5839091).

a. With respect to claim 3, KALRA discloses a sample (specimen) is placed on the at least one slide (Column 13, lines 52-54) but does explicitly disclose the optical sensor adapted to record an image of the finalized slide. However, RHETT teaches an apparatus for automatic slide staining in which the optical sensor (CCD camera) is adapted to record an image of the finalized slide after said slide has been subjected to a staining protocol (Column 14, lines 5-8). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of KALRA to include the

optical sensor recording an imaged of the finalized slide because it allows for the recalling of a complete history of each slide for analysis and diagnosis (Column 14, lines 5-9).

b. With respect to claim 4, KALRA discloses at least one element provided on the at least one removable reagent container and the at least one slide; wherein at least one element comprises a bar code (Column 8, lines 1-10).

c. With respect to claim 5, KALRA discloses the optical sensor is configured to identify an individual identification feature of the sample (bar code) (Column 8, lines 20-21).

7. Claims 17-19, 21-23, 25, 27-30, 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over KALRA (US 5948359) in view of TSEUNG (US 2003/0099573) and WANG (US 5900045) as applied to claims 1-2, 6-8, 10-12, 14-16 and 36 above, and further in view of GANZ (WO 02/064812).

a. With respect to claim 17, KALRA discloses the claimed invention (see rejection of claim 1 above) except for a computer image biological analysis element and the optical sensor recording a first before image and a second after image. However GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2) and an optical sensor (camera) that records a first image of the sample before staining and records a second image of the sample after staining (Page 6, Paragraph 2 and Page 3, Paragraph 1). At the time of the invention it would have been

obvious to one of ordinary skill in the art to modify the apparatus of KALRA to include the computer image analysis and two image recordings as taught by GANZ because before staining it allows for adjustment to the positions of the slides to ensure accurate placement of the reagent on the slide (Page 6, Paragraph 2) and after it allows for determination of if the slides were properly stained (Page 10, Paragraph 2). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer

has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

b. With respect to claims 18-19, GANZ teaches the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).

c. With respect to claim 21, KALRA discloses the claimed invention (see rejection of claim 1) including the sample being placed on a slide in a removable slide rack (slide holder) (Column 5, lines 31-34) and wherein the control element to which said robotic

element is responsive and monitors insertion or removal of the slide rack during processing protocol steps (Column 5, lines 43-48, Column 8, lines 20-25, Column 16, lines 46-63); but does not explicitly disclose recording relevant image data and feeding the data to a control element to which the robotic element is responsive, or biologically analyzing image data of the sample with a computer. However GANZ teaches a staining apparatus with a camera with a control computer that records relevant image data (image of the sample) and feeds the data to a control element (computer) (Page 6, Paragraph 2 and Page 3, Paragraph 1) which has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of KALRA to include the computer image analysis as taught by GANZ because it allows for determination of if the slides were properly stained (Page 10, Paragraph 2). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one

of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing

during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

d. With respect to claims 22-23, GANZ teaches the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).

e. With respect to claim 25, KALRA teaches a method of staining tissue sample in an automatic apparatus (see rejection of claims 6 and 7) including providing at least one removable sample on at least one slide positioned within a slide section (Column 5, lines 31-34) but does not explicitly disclose recording relevant image data and feeding the data to a control element to which the robotic element is responsive, or biologically analyzing image data of the sample with a computer. However GANZ teaches a staining apparatus with a camera with a control computer that records relevant image data (image of the sample) and feeds the data to a control element (computer) (Page 6, Paragraph 2 and Page 3, Paragraph 1) which has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of KALRA to include the computer image analysis as taught by GANZ because it allows for determination of if the slides were properly stained (Page 10, Paragraph 2). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-

0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or

removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

f. With respect to claims 27-28, GANZ teaches providing the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).

g. With respect to claim 29, GANZ teaches the step of storing an image relevant to a process of staining tissue samples (Page 6, Paragraph 2).

h. With respect to claim 30, KALRA discloses the claimed apparatus (see rejection of claim 1) but does not explicitly disclose the robotic element comprises a multifunction optical sensor or computer image biological analysis element. However GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2) and a multifunction optical sensor (read barcodes and inspect the positioning and alignment of a slide) configured capable of automatically identifying new slides and reagent bottles loaded into the apparatus during the staining process as taught by KALRA (Page 6, Paragraph 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of KALRA to include

the computer image analysis as taught by GANZ because it allows for determination of if the slides were properly stained (Page 10, Paragraph 2) and having one optical sensor to complete multiple functions would save on space and manufacturing costs. The combined device of KALRA and GANZ would be capable of automatically identifying insertion of new slides and reagent containers into the staining apparatus as these are the functions of the optical sensor of KALRA which reads barcodes and would be capable of being preformed by the multifunctional sensor of GANZ as it also reads barcodes. KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or

removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

i. With respect to claim 32-33, GANZ teaches the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).

j. With respect to claim 34, GANZ teaches a stored image relevant to a process of staining tissue samples (Page 6, Paragraph 2).

8. Claims 9 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over KALRA (US 5948359) in view of TSEUNG (US 2003/0099573) and WANG (US 5900045) as applied to claims 1-2, 6-8, 10-12, 14-16 and 36 above, and further in view of BERNSTEIN (US 5696887).

a. With respect to claim 9, KALRA discloses the claimed invention (see rejection of claim 1) but does not explicitly disclose a first and second slide section separated by the reagent section. However, BERNSTEIN teaches an apparatus for automated tissue assay in which samples are located in two sections which are separated by an element (Figure 2). BERNSTEIN further discloses the importance of reducing the time it takes to process slides in order to multitask and more efficiently stain multiple slides in a shorter period of time (Column 27, lines 15-67) which would require reducing the amount of space between the slide racks and processing stations with reagents. At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the arrangement of slides separated by a reagent section as disclosed by BERNSTEIN because it allows for the robotic device to have sufficient degrees of freedom to reach each slide and processing station with suitable movement (Column 4, lines 30-41) and allows for a reduction in processing time of slides by optimizing work station module locations (Column 27, line 15-Column 28, line 44). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses

an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and

used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

b. With respect to claim 35, KALRA discloses the claimed invention (see rejection of claim 1) but does not explicitly disclose a first and second slide section separated by the reagent section. However, BERNSTEIN teaches an apparatus for automated tissue assay in which samples are located in two sections which are separated by an element (Figure 2). BERNSTEIN further discloses the importance of reducing the time it takes to process slides in order to multitask and more efficiently stain multiple slides in a shorter period of time (Column 27, lines 15-67) which would require reducing the amount of space between the slide racks and processing stations with reagents. At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the arrangement of slides separated by a reagent section as disclosed by BERNSTEIN because it allows for the robotic device to have sufficient degrees of freedom to reach each slide and processing station with suitable movement (Column 4, lines 30-41) and allows for a reduction in processing time of slides by

optimizing work station module locations (Column 27, line 15-Column 28, line 44). KALRA does not explicitly disclose the reagent rack is removable below the plane of the robotic element during dispensing of at least one reagent. However, TSEUNG discloses an automated tissue staining system comprising slides in a slide section, a robotic delivery system above the reagent section, a control element (0026-0028), and removable reagent containers held in a reagent rack within a reagent drawer (reagent section) slidably mounted for in and out movement in the Y-direction (removable below the plane of the robotic element) with the reagent drawer situated to enable a reagent container to be added or removed without interrupting the dispensing of the robotic element (capable of not interfering due to location below robotic delivery) (0035-0037, Figure 1, 3). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of KALRA to include the reagent racks in slide drawers below the robotic element as taught by TSEUNG because it facilitates the exchange of reagents while limiting the impact on the controlled environment within the processing space and permits a user-convenient and independent access to the slides or reagent containers (0036-0037). KALRA discloses the control element is configured to monitor insertion or removal of the multiple removable reagent containers during the staining process (Column 5, lines 43-48, Column 16, lines 46-63) and TSEUNG discloses the autostainer has a control system that implements software that accepts and effectuates a series of process steps or protocol regarding reagent containers (0034, 0028-0030, 0051-53), which both controllers are capable of being programmed through their software as desired, to allow for continued movement and dispensing during replacement of one of

the reagent containers. Neither KLARA nor TSEUNG explicitly disclose the programming of the controller to continue movement and dispensing during processing. However, WANG discloses a liquid dispensing line controlled by a control device and used in an automated process in which fluid dispensing is operated so that it alternates to a full liquid reservoir (reagent container) so that refill or maintenance (insertion or removal) of one liquid reservoir can be conducted at anytime without interrupting the normal operation (controller configured to) of the liquid dispensing (continue movement and dispensing) (Column 2, lines 6-12 and Column 4, lines 48-65). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the controller of KALRA and TSEUNG to include being configured to continue dispensing during replacement of the reagent container as taught by WANG because it eliminates potential downtime of the dispensing (Column 2, lines 6-12).

Response to Arguments

9. Applicant's arguments with respect to claims 1-12, 14-19, 21-23, 25, 27-30 and 32-36 have been considered but are moot in view of the new ground(s) of rejection with the applied additional reference directed to WANG (US 5900045).

10. In response to applicant's argument on page 20, that TSEUNG teaches the opposite of the amended claim limitation, the examiner disagrees. The portion of TSEUNG (paragraph 34) that applicant claims teaches away refers to the option the user has of pausing the processing in order to add priority or stat slides to the slide protocol which is not relevant to the limitation added to the claims which is directed to allowing the continuation of movement and dispensing during

reagent addition or removal from the system. TSEUNG can not be said to teach away from this limitation as the disclosure is silent with regards to the software programming regarding adding or removal of reagents during processing.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. O'Keefe (US 5573727) and Young (US 3912456) also disclose placing slides or reagents on removable racks in drawers below a staining apparatus.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIELLE HENKEL/
Examiner, Art Unit 1775

/William H. Beisner/
Primary Examiner, Art Unit 1775